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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,586	11/30/2000	Michael Kock	49100	5846
26474	7590	09/22/2004	EXAMINER	
KEIL & WEINKAUF 1350 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036			HUTSON, RICHARD G	
			ART UNIT	PAPER NUMBER

1652

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,586

Applicant(s)

KOCK ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-32 is/are pending in the application.
- 4a) Of the above claim(s) 5-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/1/2004 has been entered.

Applicants amendment of claims 1-3, in the paper of 3/1/2004, is acknowledged. It is further noted that in applicants amendment of 3/1/2004, applicants have amended claims 2 and 3, yet in the status of claims 2 and 3, as indicated prior to the claim in parenthesis, applicants state "(previously presented)", whereas this should be "(currently amended)". Claims 1-3 and 5-32 are still at issue and are present for examination.

Applicants' arguments filed on 3/1/2004, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Election/Restrictions

Applicants comments regarding the previously submitted petition as well as the decision to this petition are acknowledged. It is acknowledged that previously distinct

groups V (claims 6-10) and VI (claim 11), by virtue of applicants petition have been combined.

Claims 5-32 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed.

Specification

The disclosure remains objected to because of the following informalities:

As discussed previously, under information disclosure statement, the reference Kupper et al., does not include the appropriate Journal, Volume and Page information. It is requested that this information be added.

Appropriate correction is required.

Claim Objections

Claims 1 remains objected to because of the following informalities:

Claims 1 continues to contain non-elected subject matter (i.e. SEQ ID NOs: 4, 6, 8 and 10).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is hereby withdrawn based on applicants amendment of claim 1 such that the claimed functional equivalents must exhibit poly(ADP-ribose)-synthesizing activity.

This rejection was stated in the previous office actions as it applied to claims 1-3. In response to this rejection, applicants have amended claims 1-3 and argue the rejection as it applies to the newly amended claims. It is noted that as discussed above claim 1 has been dropped from this rejection, however, claims 2 and 3 remain rejected for the reasons previously stated.

Applicants submit that the claims have now been amended to clarify the structural and functional features present in the claimed functional equivalents (i.e. having poly(ADP-ribose) synthesizing activity). As discussed above and herein, this necessary functional limitation only applies to claim1, not claims 2 and 3. It is noted that both claims 2 and 3 are currently drawn to "A functional equivalent of a PARP homolog as claimed in claim1..." with specific additional structural limitations. While claim 1 is drawn to PARP homologs which must have a specifically defined functional activity of poly (ADP-ribose)-synthesizing activity, this functional activity is not a necessary limitation of the "functional equivalents" of claims 2 and 3, and thus these claims remain

rejected for the reasons previously associated with the indefiniteness of “functional equivalents”.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-3 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was stated in the previous office action as it applied to previous claims 1-3. In response to this rejection, applicants have amended claims 1-3 and argue the rejection as it applies to the newly amended claims. As discussed above under the 112 second paragraph rejection it is noted that the rejection of claim 1 is withdrawn based on applicants amendment of claim 1. However, for the reasons stated above and previously the rejection of claims 2 and 3 remain because applicants continue to claim “functional equivalents” of the PARP homologs claimed in claim 1, which include undefined and thus inadequately described “functional equivalents”. Applicants submission that the “functional equivalents now have significant functional homology...” is not found persuasive. It remains unclear and inadequately described what functional homology the claimed genus of claims 2 and 3 have.

Applicants argument is not found persuasive because as is discussed above there remains some question with respect to what applicants intend in the meaning of “functional equivalents thereof” and further along this line of reasoning, applicants have not defined any function/activity of the claimed “functional equivalents of PARP homologs”, thus applicants have not disclosed any particular structure to function/activity relationship for the disclosed species as it relates to the claimed genus. The inclusion of such a function/activity limitation combined with applicants structural limitations would help applicants overcome this rejection.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-3 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a poly(ADP-ribose) polymerase (PARP) homolog comprising the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for any “functional equivalent” of a poly(ADP-ribose) polymerase (PARP) homolog comprising a functional NAD⁺ binding domain with the sequence $PX_n(S/T)GX_3GKGIYFA$, and lacking any zinc finger motif with the sequence $CX_2CX_MHX_2C$, wherein M is 28 or 30, and functional equivalents thereof, having 85% homology to SEQ ID NO: 2 and exhibiting poly(ADP-ribose)-synthesizing activity. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was stated in the previous office action as it applied to previous claims 1-3. In response to this rejection, applicants have amended claims 1-3 and continue to argue the rejection as it applies to the newly amended claims.

Applicants traverse the rejection in part, as above on the basis that given applicants amendment with respect to this rejection as based on an imprecision in denoting proper functionality, applicants submit that applicants amendment has successfully overcome such an issue. It is noted that any such basis of the rejection (i.e. based on an imprecision in denoting proper functionality) would only be overcome by applicants amendment of claim 1, not claims 2 and 3 as discussed above. Thus claims 2 and 3 remain rejected in part on the basis of the imprecision in denoting proper functionality.

Applicants further traverse this rejection on the basis that structural homology of 85% at the amino acid level with functional equivalency is not uncommon for the skilled artisan to achieve in the present art.

Applicants complete argument is acknowledged, however, found non persuasive for the reasons stated previously and above. Further while applicants may argue that it is not "uncommon to achieve structural homology of 85% at the amino acid level with functional equivalency", applicants have not provided sufficient guidance to enable the breadth of those claims drawn to those molecules having 85% structural homology to

the specified SEQ ID NOs. (claim 1), nor to those molecules encompassed by the “functional equivalents” of claim 1 (claims 2 and 3).

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the allowed number of amino acid modifications of any poly(ADP-ribose) polymerase. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Thibodeau et al. (Biochem. Cell Biol, Vol 67, pages 653-660, 1989).

Thibodeau et al. teach the cloning of a rodent cDNA encoding the poly(ARP) polymerase catalytic domain. The encoded protein comprises a NAD⁺ binding domain which has the amino acid sequence of SEQ ID NO: 11, but does not comprises SEQ ID

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NO: 30. The encoded protein further comprises the amino acid sequence of SEQ ID NO: 12 and SEQ ID NO: 18 and is a "functional equivalent of a PARP homolog as claimed in claim 1" (i.e. SEQ ID NO: 2). It is noted to applicants that as discussed above under the 112 second paragraph rejection, applicants amendment of claims 2 and 3 has resulted in claims 2 and 3 being drawn to a much broader genus than claim 1. The reference in claims 2 and 3, to claim 1 is noted, however, it is also noted, as discussed above, that the limitations of claim 1 are not incorporated into claims 2 and 3 by virtue that claims 2 and 3 are drawn to "functional equivalents of a PARP homolog as claimed in claim 1". Thus Thibodeau et al. anticipates claims 2 and 3.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a long horizontal flourish extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
9/14/2004